Certificate of Mailing

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Date: March 1, 2004

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Rena J. Barrett

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:

Braj Bhusan Lohray et al.

CASE NO.: CHL-102 (C)

APPLICATION NO.: TBD

GROUP ART UNIT: 1626

FILED: TBD

EXAMINER: Sonya A. Wright

FOR: NOVEL HETEROCYCLIC COMPOUNDS, THEIR PREPARATION,

PHARMACEUTICAL COMPOSITIONS CONTAINING THEM AND THEIR USE IN

MEDICINE

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1 .97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(X) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required. The Commissioner is authorized to charge any fees required to Deposit Account No. 03-3975.

CHL-102(C) Patent

() In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

- () Certification in Accordance with §1.97(e) is set forth below.
- () The fee of \S as set forth in $\S1.17(p)$ is attached.
- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.31 1 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of § as set forth in §1.17(i)(1).

The present Information Disclosure Statement pertains to the following references listed on attached PTO-1449, pages 1-7. Copies of said references were previously submitted to the United States Patent Office in the co-pending parent Patent Application, Serial No. 09/928,242 (Attorney Docket Number CHL-102) and co-pending Continuation-in-Part, Serial No. 10/200,107 (Attorney Docket Number CHL-102.1(CIP)).

It is respectfully requested that the Examiner return a copy of the attached form PTO-1449 with initials or remarks as appropriate after consideration of the disclosed materials.

Please charge any necessary fees to Deposit Account No. 033-975.

There are no listed references which are not in the English language or do not contain an English language abstract.

Respectfully submitted,

Hans-Peter G. Hoffmann, Reg. No. 37,352

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FORM PTO-1449 (Modified)	ATTY. DOCKET NO.:	SERIAL NO.:		
IST OF PATENTS AND PUBLICATIONS FOR PPLICANT'S INFORMATION DISCLOSURE STATEMENT	CHL-102(C) [TBD] APPLICANT: LOHRAY, et al.			
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US PATENT DOCUMENTS

Exam Init	Ref Des	Document No.	Issue Date	Name	Class	Sub Class	FILING DATE If Appropriate
	1.	5,089,514	02/18/92	Hulin			
	2.	5,306,726	04/26/94	Hulin			
	3.	5,985,884	11/16/99	Lohray, et al.			
	4.	6,048,883	4/11/2000	Haigh, et al.			
	5.	6,054,453	4/25/2000	Lohray, et al.			
	6.	6,130,214	10/10/2000	Lohray, et al.			
	7.	6,166,049	12/26/2000	Smith			

FOREIGN PATENT DOCUMENTS

		Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Transl Yes	lation No
•	8.	EP 0753 298	01/15/97	Tsujita, et al.				
	9.	EP 90 3343	03/24/99	Nagao, et al.				1
	10.	WO 91/19702	12/26/91	Hulin				
	11.	WO 94/01420	01/20/94	Haigh, et al.				
	12.	WO 94/13650	06/23/94	Haigh				
	13.	WO 94/29302	12/22/94	Faller				
	14.	WO 95/03038	02/02/95	Goldberg, et al.				
	15.	WO 95/17394	06/29/95	Cantello, et al.				
	16.	WO 96/04260	02/15/96	Haigh				
	17.	WO 96/04261	02/15/96	Haigh	-			
	18.	WO 96/33998	10/31/96	Terasawa, et al.			1	
	19.	WO 97/25042	07/17/97	Smith				
	20.	WO 97/31970	09/04/97	Hammer, et al.				
	21.	WO 97/36579	10/09/97	Willson				
	22.	WO 98/02159	01/22/98	Poste, et al.				
	23.	WO 98/28534	07/02/98	Kim, et al.				
	24.	WO 99/08501	02/25/99	Lohray, et al.				
,	25.	WO 99/16758	04/08/99	Lohray, et al.				
	26.	WO 99/19313	04/22/99	Lohray, et al.				
-	27.	WO 99/20614	04/29/99	Lohray, et al.				
	28.	WO 99/38850	08/05/99	Lohray, et al.				
	29.	WO 00/23417	04/27/2000	Jeppesen, et al.				
	30.	WO 00/23445	04/27/2000	Jeppesen, et al.			1	
	31.	WO 00/23451	04/27/2000	Jeppesen, et al.				1
	32.	WO 01/53257	07/26/2001	Lohray, et al.			Ť .	

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LIST OF PATENTS AND PUBLICATIONS FOR	CHL-102(C) [TBD]		
APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT: LOHRAY, et al.		
Page 2 of 7	FILING DATE: March 1, 2004	GROUP: 1626	

33.	A. N. Collins, G. N. Sheldrake and J. Crosby, in "Chirality in Industry II", John Wiley
34.	& Sons, Inc., 1997, 81-98 and references therein Cancer Research, 58, 3344-3352 (1998)
35.	Carcinogenesis, vol. 19 no. 11, 1949-1953 (1998)
36.	Cell, 87, 377-389 (1996)
37.	Cell, 55, 932-943 (1999)
38.	Cell, 79, 1147-1156 (1994)
39.	Cell, 83, 803-812 (1995)
40.	Cell, 99, 239-242 (1999)
41.	Cell Biology, 95, 14751-14756 (1998)
42.	Current Biol., 5, 618-621 (1995)
. 43.	E. L. Eliel and S. H. Wilen, in "Stereochemistry of Organic Compound", John Wiley & Sons, Inc., 1994, 297-464 and references therein
44.	Endocrine Reviews, 20(5), 649-688 (1999)
45.	Endocrinology 135, 798-800 (1994)
46.	Exp. Clin. Endocrinol. Diabetes: 109(4), S548-559 (2001)
47.	T. W. Greene and P. G. M. Wuts "Protective Groups in Organic Synthesis", John Wiley & Sons, Inc., 1999, 3 rd Ed., 201-245 along with references therein
48.	J. Clin. Invest., 85, 962-967, 1990
49.	J. Medicinal Chemistry, 43(4), 527-550 (2000)
50.	Jaques et al. "Enantiomers, Racemates and Resolution", Wiley Interscience, 1981
51.	Knorr, L., Ber., 1885, 18, 299-311
52.	Macikinnon et al., J. Biol. Chem. 261, 2548-2552 (1986)
. 53.	Med. Res. Rev., 20(5), 350-366 (2000)
54.	Miller et al., Br. Med. J. 282, 1741-1744 (1981)
55.	Molecular Cell, 465-470 (1998)
56.	Nature Reviews: Drug Discovery: 1(4), 276-86 (2002)
57.	Nature, 405, 421-424 (2000)
58.	Paal C. Ber., 1885, 18, 367-371

FORM PTO-1449 (Modified)	ATTY. DOCKET NO.:	SERIAL NO.:
LIST OF PATENTS AND PUBLICATIONS FOR	CHL-102(C)	[TBD]
APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT: LOHRAY, et al.	
Page 3 of 7	FILING DATE: March 1, 2004	GROUP: 1626

59.	Petit D., Bonnefis M. T., Rey C. and Infante R., Effects of ciprofibrate on liver lipids and lipoprotein synthesis in normal and hyperlipidemic rats, Atherosclerosis, 74, 215-225 (1988)
60.	Picardo et al., Arteriosclerosis, 6, 434-441 (1986)
61.	Principles of Asymmetric Synthesis J E Baldwin Ed. Tetrahedron series, Volume 14, Page no. 311-316
62.	Proc. Natl. Acad. Sci. 93, 5793-5796 (1996)
63.	Proc. Natl. Acad. Sci., 94, 237-241 (1997)
64.	Remington: the Science and Practice of Pharmacy, 19 th Ed., 1995
65.	Ross and Glomset, New Engl. J. Med., 295, 369-377 (1976)
66.	Science, 269, 543-46 (1995)
67.	R. A. Sheldon, in "Chirotechnology", Marcel Dekker, Inc. NY, Basel, 1993, 173-204 and references therein
68.	Stampfer et al., N. Eng. J. Med., 325, 373-381 (1991)
. 69.	Trends Endocrine. Metabolism, 4, 291-296 (1993)
70.	Trends in Pharmacological Sci., 469-473 (2000)
71.	Trinder, P. Ann. Clin. Biochem. 1969. 6: 24-27
72.	Wieland, O. Methods of Enzymatic Analysis. Bergermeyer, H., O., Ed., 1963. 211-214

FORM PTO-1449 (Modified)	ATTY. DOCKET NO.:	SERIAL NO.:
LIST OF PATENTS AND PUBLICATIONS FOR	CHL-102(C)	[TBD]
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US PATENT DOCUMENTS

Exam	Ref		Issue			Sub	FILING DATE
Init	Des	Document No.	Date	Name	Class	Class	If Appropriate
	73.	5,861,173	01/19/1999	Nishioka, et al.		1	<u> </u>
	74.	5,885,997	03/23/1999	Lohray, et al.			
	75.	5,889,025	03/30/1999	Lohray, et al.			
	76.	5,889,032	03/30/1999	Lohray, et al.			
	77.	6,130,214	10/10/2000	Lohray, et al.			
	78.	6,159,966	07/24/2001	Lohray, et al.			
	79.	6,265,401	07/24/2001	Lohray, et al.			
	80.	6,294,586	09/25/2001	Yelle, et al.			
	81.	6,313,113	11/06/2001	Lohray, et al.			
	82.	6,362,360	03/26/2002	Andersson, et al.			
	83.	6,369,067	04/09/2002	Gurram, et al.			
	84.	6,440,961	08/27/2002	Lohray, et al.			
	85.	6,444,816	09/03/2002	Das, et al.			
-	86.	6,521,622	02/18/2003	Ricks, et al.			
	87.	6,525,083	02/25/2003	Acton, III, et al.			
	88.	6,569,901	05/27/2003	Mogensen, et al.			
	89.	6,573,628	05/03/2003	Sloupensky, et al.			
	90.	6,589,969	07/08/2003	Tajima, et al.			
	91.	6,602,901	08/05/2003	Jeppesen, et al.			

FOREIGN PATENT DOCUMENTS

Country &	Pub.		Sub	Translation
Doc. No. (11)	Date (43)	Class	Class	Yes No

FORM PTO-1449 (Modified)	ATTY. DOCKET NO.:	SERIAL NO.:
LIST OF PATENTS AND PUBLICATIONS FOR	CHL-102(C)	[TBD]
APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT: LOHRAY, et al.	
Page 5 of 7	FILING DATE: March 1, 2004	GROUP: 1626

92.	DDT, Vol. 6, No. 13, 2001, page 654-55, "Unravelling metabolic syndrome X."
93.	Diabetes Mellitus - A Fundamental Text book, pages 326-329,611-613,
	"Definition and Classification of Diabetes Mellitus and the New Criteria for Diagnosis."
94.	Am Heart J. 1988 Dec; 116(6 Pt 2): 1713-24
	"The Prospective Cardiovascular Munster (PROCAM) study: prevalence of hyperlipidemia in
	persons with hypertension and/or diabetes mellitus and the relationship to coronary heart
	disease."
95.	3rd Report of the National Cholesterol Education Program (NCEP), Expert
	Panel on 'Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult
	Treatment Panel III)'- NIH, USA.
96.	Diabetes Mellitus - A Fundamental Text book, pages 326-329, 611 -613, "Fatty Acids and
	Insulin Resistance."
. 97.	Ann NY Acad Sci. 1999 Nov 18; 892:25-44,
	"Etiology of the metabolic syndrome: potential role of insulin resistance, leptin resistance, and
	other players."
98.	Horm Metab Res. 2003 Feb; 35(2); 92-96,
	"Leptin levels in type 2 diabetes: associations with measures of insulin resistance and insulin
	secretion."
99.	Metabolism. 2003 Jun; 52(6):713-9,
	"Relative impact of insulin resistance and obesity on cardiovascular risk factors in polycystic
	ovary syndrome."
100.	The Journal of Clinical Endocrinology & Metabolism 2003, 88(5):2031-2036,
	"Glucose Intolerance, Insulin Resistance, and Hyperandrogenemia in First
	Degree Relatives of Women with Polycystic Ovary Syndrome."
101.	Diabetes Care. 2003 Jun; 26(6): 1752-8,
	"Type 2 Diabetes and Subsequent Incidence of Breast Cancer in the Nurses"
	Health Study."
102.	Exp Biol Med (Maywood). 2003 Apr; 228(4): 396-405, "Insulin resistance and its contribution
	to colon carcinogenesis."
103.	Cancer Epidemiology, Biomarkers & Prevention. 2000 Dec.; 9:1271-79. "Possible
	Mechanisms Relating Diet and Risk of Colon Cancer."
104.	Pol Arch Med Wewn. 1998 Aug; 100(2):125-32,
	"Bone density in type 2 diabetes as related to obesity and adrenal f unction."
105.	FEBS Lett. 2000 Apr 7;471(1):119-24,
	"Peroxisome proliferator-activated receptor activators modulate the osteoblastic maturation of
	MC3T3-E1 preosteoblasts."
106.	Endocrinology 1999; 140(11): 5060-65,
,	"Thiazolidinediones inhibit osteoclast-like cell formation and bone absorption in vitro."

FORM PTO-1449 (Modified)	ATTY. DOCKET NO.:	SERIAL NO.:
LIST OF PATENTS AND PUBLICATIONS FOR	CHL-102(C)	[TBD]
APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT: LOHRAY, et al.	
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	107.	(including Author, Title, Date, Pertinent Pages, Publication, Etc.)
	107.	Am J Surg. 1995 Jan; 169(1): 105-9,
		"Alterations in hepatocyte insulin binding in chronic pancreatitis: effects of pancreatic
		polypeptide."
	108.	J Clin. Endocrinol. Metab. 2001 May; 86(5): 2289-95, "Dyslipidemia in familial partial
		lipodystrophy caused by an R482W mutation in the LMNA gene."
109.		Clin Nephrol. 2000 Nov; 54(5): 366-73,
		"Mild renal dysfunction is associated with insulin resistance in chronic glomerulonephritis."
110.		J Am Soc Nephrol. 2002 Jul; 13(7): 1894-900,
		"Insulin Resistance as an Independent Predictor of Cardiovascular Mortality in Patients with
		End-Stage Renal Disease."
	111.	Kidney Int. 2002 Sep; 62(3): 963-70,
		"Nephropathy in type 1 diabetes: a manifestation of insulin resistance and
_		
•		multiple genetic susceptibilities? Further evidence from the Pittsburgh
		Epidemiology of Diabetes Complication Study."
ď	112.	Aliment Pharmacol Ther. 1999 Feb; 13(2): 209-17,
		"Glucose metabolism and insulin sensitivity in inactive inflammatory bowel disease."
	113.	J Am Acad Dermatol. 1985 Jul; 13(1): 1-30,
		"Xanthomas and hyperlipidemias."
	114.	The Journal of Clinical Endocrinology & Metabolism 2003; 88(6):2422-2429,
		"The Potential Influence of Inflammation and Insulin Resistance on the
		Pathogenesis and Treatment of Atherosclerosis-Related Complications in Type 2 Diabetes."
	115.	J Clin Endocrinol Metab 2003; 88: 2412-2421,
		"The Metabolic Syndrome : Peroxisome Proliferator-Activated Receptor Y and Its Therapeutic Modulation."
	116.	J Clin Pract Suppl. 2003 Mar; (134):10-7,
		"Inflammation, the metabolic syndrome and cardiovascular risk."
	117.	Cuff Drug Targets Cardiovasc Haematol Disord. 2001 Dec; 1(2): 107-20,
		"Reduction and prevention of the cardiovascular sequelae of the insulin
		resistance syndrome."
	118.	The Journal of Clinical Endocrinology & Metabolism 88(6):2399-2403,
		"Insulin Resistance/Compensatory Hyperinsulinemia, Essential Hypertension, and
	119.	Cardiovascular Disease." Endocrinology 2003; 144(6) 2201-2207,
•	119.	"Minireview: Lipid Metabolism, Metabolic Diseases, and Peroxisome
		Proliferator-Activated Receptors."
•	120.	Am J Manag Care. 2002 Dec; 8(20 Suppl):S635-53, "The metabolic syndrome, type 2 diabetes
		and cardiovascular disease: understanding the role of insulin resistance."
	121.	Am J Health Syst Pharm. 2002 Dec 1;59 Suppl 9:S9-13, "Treating dual defects in diabetes:
		insulin resistance and insulin secretion."
ı	122.	Endocrinol Metab Clin North Am. 2001 Dec;30(4):935-82, "Insulin therapy in type 2
		diabetes."

FORM PTO-1449 (Modified)	ATTY. DOCKET NO.:	SERIAL NO.:
LIST OF PATENTS AND PUBLICATIONS FOR	CHL-102(C)	[TBD]
APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT: LOHRAY, et al.	
Page 7 of 7	FILING DATE: March 1, 2004	GROUP: 1626

	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
123.	J Hypertens Suppl. 2001 Sep;19 Suppl 3:S17-21,
	"The choice of first-line therapy: rationale for low-dose combinations of an
	angiotensin converting enzyme inhibitor and a diuretic."
124.	Diabetes Obes Metab. 1999 May; 1 Suppl 1:S41-8,
	"Promising new approaches."
125.	J Hypertens Suppl. 1998 Jan;16(1):S35-7,
126.	"Obesity in hypertension: effects on prognosis and treatment."
120.	Nurse Pract. 1996 Jun;21(6):74-5, 79-80, 83-6,
127.	"Syndrome X. Recognition and management of this metabolic disorder in primary care."
	Postgrad Med. 2003 May;Spec No:27-34,
120	"Insulin resistance syndrome. Description, pathogenesis, and management."
128.	Am J Cardiol. 2003 Apr 3;91(7A):18E-39E,
	"Effects of Nonstatin Lipid Drug Therapy on High-Density Lipoprotein Metabolism."
129.	Am J Cardiol. 2003 Apr 3;91(7A):18E-39E,
•	"Management of Patients with diabetic hyperlipidemia."
130.	Am J Cardiol. 2003 Apr 3;91(7A):18E-39E,
	"Treatment of patients with Metabolic Syndrome."
131.	Cardiovasc Drugs Ther. 2002 Sep;16(5):457-70,
	"Beta-blockers and diabetes: the bad guys come good."
132.	Curr Drug Targets. 2002 Jun; 3(3): 203-21,
	"Multiple drug targets in the management of type 2 diabetes."
133.	Annals of Internal Medicine, 1999, Aug; 131(4): 281-303,
	"Pharmacologic Therapy for Type 2 Diabetes Mellitus."
134.	Diabetes Mellitus - A Fundamental Text book, page 769-811,
	"Insulin Secretogogues Sulfonylureas and Meglitinides."
135.	Detection Evaluation and Treatment of High Blood Cholesterol in Adults
	(Adult Treatment Panel 111)-"Drug Therapy."
136.	Int J Clin Pract Suppl. 2000 Oct; (113): 54-62,
	"Current treatment of insulin resistance in type 2 diabetes mellitus."
137.	Diabet Med. 1998; 15 Suppl 4:S13-9,
	"Improving glycaemic control with current therapies."
138.	Am J Manag Care. 2002 Oct; 8(16 Suppl): S460-71,
•	"Current treatment approaches to type 2 diabetes mellitus: successes and shortcomings."